DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 1, 2015

Terumo Europe N.V.
Ms. M. J. Aerts
Regulatory Affairs Manager
Interleuvenlaan 40
3001 Leuven
BELGIUM

Re: K150263
Trade/Device Name: K-Pack II Needle - 21G x 2"
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: March 9, 2015
Received: March 12, 2015

Dear Ms. Aerts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K150263

Indication for Use

510(k) Number (if known):

Device Name: K-Pack II Needle - 21G x 2”

Indication For Use:

The 21G x 2” K-Pack II Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY as required by 807.92

Submitter information

Prepared for:	**TERUMO EUROPE N.V.** **Interleuvenlaan 40,** **3001 Leuven,** **BELGIUM**
Prepared by/Contact person:	**Mrs. M.J. Aerts – Manager Regulatory Affairs** **Tel. (+32) 16 38 13 53** **Fax (+32) 16 40 02 49**
Date prepared:	**March 2015**

II.1. Device Name

Proprietary Name

K-Pack II Needle - 21G x 2”

Classification Name

Hypodermic Single Lumen Needle

21CFR, Section 880.5570

Classification: Class II

Product Code

FMI

II.2. Predicate Devices

The following cleared devices are selected as predicate devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)

II.3. Reason for Submission

This 510k is being submitted to extend the cleared K-Pack II Needle (K984576) product line with the K-Pack II Needle - 21G x 2”.

The 21G x 2” K-Pack II Needle is the same needle as the cleared 21G x 2” Neolus Needle covered in K001572. The only difference is that the Neolus Needle is packed in a blister pack while the K-Pack II Needle is packed in a hard pack consisting of a cap and a case.

The packaging of the 21G x 2" K-Pack II Needle is the same as the packaging of the cleared K-Pack II Needles covered in K984576. The only difference is that the case is longer (50 mm) compared to what has been cleared before (25 mm and 40 mm).

The 21 x 2" Gauge needle is also the same as the cleared 21 Gauge K-Pack II Needle covered in K984576 with the only difference of having a longer needle and a longer case as the cleared needle.

This Special 510k is being submitted due to potential issues specific for the longer case of the 21G x 2" K-Pack II Needle.

This 510k will provide supporting information that the 21G x 2" K-Pack II Needles are an acceptable extension of the current K-Pack II Needle product line.

II.4. Intended Use

The 21G x 2" K-Pack II Needles being Hypodermic Single Lumen Needles are sterile medical devices for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Note: This is the same intended use as the predicate devices, K-Pack II Needle - K984576 and Neolus Needle - K001572.

II.5. Substantial Equivalence

The 21G x 2" K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)

Differences between the devices do not raise any significant issues of safety and effectiveness.

The similarities and differences are summarized in the table below.

	21G x 2" K-Pack II Needle (Terumo Europe, Belgium) (Subject of this 510k)	Neolus Needles (Terumo Europe, Belgium) (K001572)	K-Pack II Needles (Terumo Europe, Belgium) (K984576)
Intended Use	Same as predicate	Intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	Intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
Materials	Same as predicate		
Cannula	Stainless Steel	Stainless Steel	Stainless Steel
Hub	Polypropylene	Polypropylene	Polypropylene
Glue	Epoxy glue	Epoxy glue	Epoxy glue
Lubricant		Silicone	Silicone

	Silicone		
Description/ Specifications	Same as predicate	Comprised of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) designed to be connected with a male connector (nozzle) of a piston syringe.	Comprised of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) designed to be connected with a male connector (nozzle) of a piston syringe.
Needle Gauge/ length	21G x 2"	Ranging from 18G – 27G ½" – 2"	Ranging from 18G – 27G 3/8" – 1 ½"
Principle of Operation	Same as predicate	Manually	Manually
Unit packaging	Hard pack consisting of cap and long case	Blister pack	Hard pack consisting of cap and long or short case
Wall Thickness	Regular Wall	Ultra thin + thin + regular wall	Ultra thin + thin + regular wall
Sterilization	EtO to SAL 10^{-6}	EtO to SAL 10^{-6}	EtO to SAL 10^{-6}
Shelf life	5 years	5 years	5 years

II.6. Summary of Verification Activities

All necessary verification and validation tests have been performed by testing the 21G x 2" K-Pack II Needles in accordance with EN ISO 7864 (1995). Summary of the verification activities including acceptance criteria is given in the table below:

TEST	ACCEPTANCE CRITERIA
1. Cleanliness	Inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter. When examined under x2.5 magnification, the hub socket shall appear free from particles and extraneous matter.
2. Limits for acidity or alkalinity	Δ pH for K-Pack Needles extract solution is within 1 unit of the control fluid.
3. Limits for extractable metals	The extract solution of the 21G K-Pack II Needles has a content of extractable metals which is, when corrected for the metal content of the control fluid: Σ Pb, Sn, Zn, Fe ≤ 5 mg/l Cd < 0. 1 mg/l
4. Size designation	Outside diameter and nominal length are expressed in mm (and G x ").
5. Colour coding	Hub and label are colour coded following ISO 6009.
6. Conical fitting	6% luer taper, compliant with requirements of ISO 594-1 and ISO 594-2.
7. Effective needle length	The effective length = nominal length + 1.5 mm/-2.5 mm
8. Lubricant	Needles are uniformly lubricated and the silicone is not visible as droplets on the outside surface of the needle, the quantity will not exceed 0.25 mg/cm^2.
9. Needle point	The needle point of the 21G K-Pack II Needle is in the center of the bevel, is sharp and is free from extraneous matter, burr, edges and hooks.
10. Bonding strength between	The bonding strength between hub and cannula is ≥ 44N.

hub and cannula	
11. Patency of lumen	A stylet with a diameter of 0.40 mm is passing through the needle.
12. Flow rate	Tolerance on flow rate: between 80% and 125% of nominal value.

II.7. Additional Safety Information

The sterility of the 21G x 2" K-Pack II Needles is assured by using a validated sterilization method qualified in accordance with EN ISO 11135-1: "Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices", to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals".

The 21G x 2" K-Pack II Needle, like the standard K-Pack II Needle (K984576), is an Externally Communicating device, Contacting Circulating Blood, Limited Exposure (≤ 24 hrs). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing".

The expiration dating for the 21G x 2" K-Pack II Needles has been established at 5 years which is the same as the cleared K-Pack II Needles.

II.8. Conclusion

In summary, the 21G x 2" K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. Neolus Needles (K001572)

Differences between the devices do not raise any new issues of safety or effectiveness.